PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P780PC00	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/DK2004/000375	International filing date *(day/month/year)* 28.05.2004	Priority date *(day/month/year)* 30.05.2003
International Patent Classification (IPC) or national classification and IPC A61B5/103, A61B17/20, A61M37/00, A61M5/50		
Applicant ALSENSA APS et Al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30.03.2005	07.09.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Sedy, R Telephone No. +31 70 340-2978

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000375

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-19	as originally filed
Claims, Numbers	
1-29	received on 22.08.2005 with letter of 18.08.2005
Drawings, Sheets	
1/15-15/15	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 28,29

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 28,29

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000375

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-27
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-27
Industrial applicability (IA)	Yes:	Claims	1-27
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

The following documents are referred to in this communication:

D1 : DE 202 14 019 U (ROESCH AG MEDIZINTECHNIK) 16 January 2003 (2003-01-16)

D2 : WO 99/34739 A (MOELLSOEE CLAUS ;ROENBORG STEEN MEIER (DK)) 15 July 1999 (1999-07-15)

D3: US-A-5 441 490 (SVEDMAN PAL) 15 August 1995 (1995-08-15)

D4: DE 37 37 570 A (SBC SL) 3 November 1988 (1988-11-03)

D5: EP-A-0 460 327 (MIYARISAN KABUSHIKI KAISHA) 11 December 1991 (1991-12-11)

D6: US-A-5 104 375 (WOLF STEPHEN J ET AL) 14 April 1992 (1992-04-14)

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No opinion has been established regarding claims 28 and 29 since their subject-matter refers to a method for treatment of the animal body by therapy, namely (see claim 28, page 4, lines 21,22) "delivering said medicament ... to said animal." Consequently, claims 28 and 29 concern a medical method which is excluded from international preliminary examination (Article 34(4)a, Rule 67(1)(iv) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 INDEPENDENT CLAIM 1

1.1 Document D2 discloses (see e.g. page 7, line 15, page 9, lines 7-22 and page 11, lines 15-19, Figures 1-6)(the references in parenthesis applying to this document):

a) A device (1) *suitable* for delivering a medicament (20) or a diagnostic agent to the skin (5) or mucosa of an animal, the device having

b) at least one red house (2,3) and at least one separate chamber house (19),

c) wherein the rod house (2,3) having at least one housing, the at least one housing having a distal end (6) and a proximal end (12) wherein the proximal end of the rod is a needle having a tapering end (26), and at least one rod (4), the rod (4) having a distal end (9) and at least one proximal end (18), and the rod (4) being slidably arranged in the housing, the rod (4) being capable of being activated by being pushed towards the proximal end (12) of the housing, and

d) wherein the chamber house (19) has at least one chamber, a first wall of the chamber being a first sealing (22) and a second wall of the chamber being a second sealing (23), the first sealing (22) and the second sealing (23) being arranged so that an axis through the chamber may intersect both sealings (22,23), and the chamber having the medicament (20) or the diagnostic agent, wherein the chamber house (19) is connected to the rod house (2,3) so that the proximal end (18) of the rod (4) penetrates the first sealing (22) and the second sealing (23) when ~~slided~~ *slid* proximally (Figures 3 and 4).

1.2 The subject-matter of claim 1 therefore differs from this known device only in that:

the chamber house is releasably attachable to the rod house and/or attachable to the rod house through means selected from a thread, a luer lock, a bayonet lock and a snap fit lock.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

1.3 The technical problem to be solved by the present invention may therefore be regarded as making easier storage problems.

1.4 D1 clearly discloses a device suitable for delivering a medicament consisting of a chamber house (Ampulle 2) and a rod house (Grundkörper 1) being releasably attachable with each other by a threaded connection between these parts (page 9, lines 17 to 22). Additionally, since D1 also explicitly discloses (cf. page 10, lines 3 to 8) that the chamber house is attached to the rod house to prepare the injection, it also implies that these parts have been stored separately before this preparatory

step.

1.5 Moreover, the different attaching means between the chamber house and the rod house as claimed present merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to save the problem posed, namely providing means to allow ease of storage of these parts.

Therefore, the subject-matter of claim 1 does not involve an inventive step with respect to Article 33(3) PCT.

2 DEPENDENT CLAIMS 2 TO 27

2.1 Dependent **claims 2-27** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see for example:

D1, page 9, lines 7-22, for **claim 2**;
D2, passages cited in the search report, for **claims 4-7,11-18 and 27**;
D5, figure 1, for **claim 19**;
D6, column 3, lines 48-50, figures 1 and 5, for **claims 20-24**;
D4, column 1, lines 45-51, Figure 1 for **claims 25, 26**.

2.2 **Claim 6**: D1 discloses "Auslöser 6" which, when in the position as represented in Figure 1, would clearly mark that the rod has been activated.
Claims 3,8-10 define features which present several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill.

Re Item VIII
Certain observations on the international application

1 Claim 19 partially repeats the subject-matter already defined in claim 1.

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Claims amended in response to Telephone Interview (August 2005)

1. A device for delivering a medicament or a diagnostic agent to the skin or mucosa of an animal, said device comprising

at least one rod house and at least one separate chamber house, wherein said chamber house is releasably attachable to said rod house and/or attachable to said rod house through means selected from a thread, a luer lock, a bayonet lock and a snap fit lock,

wherein the rod house comprises at least one housing, said at least one housing having a distal end and a proximal end, and at least one rod, said rod having a distal end and at least one proximal end wherein the proximal end of the rod is a needle having a tapering end, and said rod being slidably arranged in the housing, said rod being capable of being activated by being pushed towards the proximal end of the housing, and

wherein the chamber house comprises at least one chamber, a first wall of said chamber being a first sealing and a second wall of said chamber being a second sealing, said first sealing and said second sealing being arranged so that an axis through said chamber may intersect both sealings, and said chamber comprising said medicament or said diagnostic agent, wherein the chamber house is connected to the rod house so that the proximal end of the rod penetrates the first sealing and the second sealing when slided proximally.

2. The device according to claim 1, wherein the rod is a longitudinal rod arranged axially in the rod house.

3. The device according to claim 1 or 2, wherein the rod house is sealed by a removable rod house sealing in the proximal end.

4. The device according to any of the preceding claims, wherein the distal end of the rod is projecting out of the distal end of the rod house.

5. The device according to any of the preceding claims, wherein the needle comprises at least one recess in the tapering portion of the needle, such as at least two recesses in the tapering portion of the needle, such as at least four recesses in the tapering portion of the needle.

6. The device according to any of the preceding claims, wherein at least one marking means is arranged in the rod house to mark that the rod has been activated.

7. The device according to claim 6, wherein the at least one marking means is a marker projecting from the distal end of the housing and said marking means is activated when the rod is activated.

8. The device according to any of the preceding claims 6-7, wherein the at least one marking means is a marker being arranged concentrically around at least a part of the distal end of the rod.

9. The device according to any of the preceding claims 6-8, wherein the marking means is coloured in a colour different from the colour of the distal end of the rod.

10. The device according to any of the preceding claims 6-9, wherein the housing comprises means for engaging the marker means when the marker means is activated.

11. The device according to any of the preceding claims, wherein means for retracting the rod after activation is arranged in the housing.

12. The device according to claim 11, wherein the means for retracting the rod is a spring.

13. The device according to any of the preceding claims, wherein the housing comprises stopper means for stopping advance of the rod at a predetermined position during activation.

14. The device according to claim 13, wherein the rod has a shoulder and the stopper means is a shoulder in the housing dimensioned to engage the shoulder on the rod.

15. The device according to any of the preceding claims, wherein the chamber house has means for being attached to the rod house.

16. The device according to any of the preceding claims, wherein the second sealing is releasably attached to the chamber house.

17. The device according to any of the preceding claims, wherein the chamber house is made from a plastic material.

18. The device according to any of the preceding claims, wherein the chamber house is made from a resilient material.

19. The device according to any of the preceding claims, wherein the chamber house is attachable to the rod house by means of a thread or snap fit lock.

20. The device according to any of the preceding claims, wherein the rod has at least two proximal ends, such as at least three proximal ends.

21. The device according to any of the preceding claims, wherein the rod house comprises at least two rods, such as at least three rods.

22. The device according to claim 21, wherein the rods are connected at their distal ends to a common activation means.

23. The device according to any of the preceding claims, wherein the device comprises at least two chamber houses, such as at least three chamber houses.

24. The device according to claim 23, wherein at least two chamber houses are connected.

25. The device according to any of the preceding claims, wherein the device is provided with a labelling means, so that the skin or the mucosa of said animal is labelled when the medicament or diagnostic agent is delivered to the animal.

26. The device according to any of the preceding claims, wherein the labelling means is arranged on the chamber house.

27. The device according to any of the preceding claims, wherein the at least one chamber is filled at least partly with medicament or diagnostic agent.

28. A method for delivering a sufficient amount of medicament or diagnostic agent to an animal in need thereof, comprising

- arranging a device as defined in any of the claims 1-27, wherein the chamber house comprising the medicament or diagnostic agent is connected to the rod house, adjacent the skin or mucosa of said animal,

- activating the rod of the device, thereby delivering said medicament or diagnostic agent to said animal.

29. The method according to claim 28, wherein the chamber house comprises an allergen or combination of allergens.

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